

D<sup>3</sup> first RNA molecule is present between the 3' region and the 5' region, under conditions suitable to provide the desired first RNA molecule in the cell.

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D<sup>4</sup> 24. (Twice Amended) The RNA molecule of claim 1, wherein said intramolecular stem is separated from said desired RNA portion by spacer sequence.

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**In the Specification:**

Please replace the current Abstract with the replacement Abstract submitted herewith.

**REMARKS**

Applicants thank Examiner Lacourciere for the courtesies extended to Applicant's representatives during the telephonic interview conducted on August 9, 2002. During the interview, Examiner Lacourciere provided helpful suggestions for acceptable amendments to the claims that would clarify the scope of coverage and more particularly point out and distinctly claim the present invention.

**Claim Amendments**

Claims 1-25 are currently pending in the application. In order to advance prosecution, Applicants have amended claims 1, 6-11, 15-18, 24. A clean version of the amended claims is shown above. A version of the amended claims with markings to show the changes made appears as Appendix A. The amendments to the pending claims were made to clarify the scope of coverage and more particularly point out and distinctly claim the present invention, in order to expedite the issuance of the claims. The amendments do not add new matter.

### **Specification**

Applicant has submitted a new abstract of the disclosure on a separate sheet, in accordance with 37 C.F.R. § 1.52(b)(4), and respectfully requests that it be included with the present application. The abstract contains no new matter.

### **Discussion of the 35 U.S.C. § 112, First Paragraph Rejection**

Claims 1-25 are rejected under 35 U.S.C. § 112, first paragraph. Without conceding to the merits of the present rejection, but solely in an effort to expedite prosecution, Applicant has amended the claims as discussed with Examiner Lacourciere during the Interview of August 9, 2002. As the amendment renders the present rejection moot, Applicant respectfully requests that the 35 U.S.C. § 112, first paragraph rejection be withdrawn.

### **Discussion of the 35 U.S.C. § 102 Rejections**

Claims 1, 9-12, 15-19, 24, and 25 are rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Inouye (U.S. Patent No. 5,208,149). Further, claims 1, 2, 9-19, 21, 24, and 25 are rejected under 35 U.S.C. § 102(e) as being allegedly anticipated by Noonberg *et al.* (U.S. Patent No. 5,624,803). These rejections are respectfully traversed.

Without conceding to the merits of the present rejection but solely in an effort to expedite prosecution, Applicant has amended the claims as discussed with Examiner Lacourciere during the Interview of August 9, 2002. The claim amendments were made to clarify the scope of coverage and more particularly point out and distinctly claim the present invention.

The amended claims are directed to a transcribed non-naturally occurring RNA molecule, comprising a desired RNA portion, wherein said desired RNA portion is present between a 3'

region and a 5' region, wherein said 3' region and said 5' region form an intramolecular stem with each other comprising at least 8 base pairs. As a non-limiting example of the invention, Applicant refers to Figure 19 of the instant Application.

Under 35 U.S.C. § 102(b), a claim is anticipated only if each and every element as set forth in the claim is found in a single art reference. *Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631, 2 USPQ2d 1051, 10533 (Fed. Cir. 1987); M.P.E.P. § 2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); M.P.E.P. § 2131.

Inouye does not anticipate claims 1, 9-12, 15-19, 24, and 25 because Inouye does not teach or suggest the presently claimed RNA molecule. Instead, Inouye describes non-naturally occurring RNA molecules with terminal stem-loop structures, wherein the desired RNA portion is located between the two terminal stem-loop structures. For example, as shown in Figure 3 of Inouye, the desired RNA is flanked by two intra-molecular stem-loop structures located at the 5' end and the 3' end. In contrast to the present invention, the 3' region and 5' region do not form an intramolecular stem with each other, as required by the amended claims. Therefore, the instantly claimed invention is distinct from the RNA molecules described in Inouye and, hence, Applicant respectfully requests that the 35 U.S.C. § 102(b) rejection be withdrawn.

Noonberg *et al.* does not anticipate claims 1, 2, 9-19, 21, 24, and 25 because Noonberg does not teach or suggest the presently claimed RNA molecule. In contrast to the presently claimed molecules, Noonberg describes a molecule with "self-complementary ends" where the oligonucleotide form "small double-stranded hairpin loops" (column 17, lines 39-41) at each end. These molecules are shown in Figure 2 as "sample transcript." However, in Noonberg, the 3' region and 5' region do not form an intramolecular stem with each other, as required by the

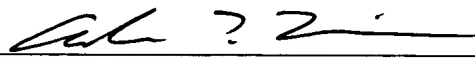
amended claims. Therefore, the instantly claimed invention is distinct from the RNA molecules described in Noonberg and, hence, Applicant respectfully requests that the 35 U.S.C. § 102(e) rejection be withdrawn.

### **Conclusion**

Applicant respectfully requests that the amendments be entered as they were made to put the claims in better form for consideration on appeal. The application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone call would expedite the prosecution of this application, the Examiner is invited to call the undersigned attorney.

Respectfully Submitted,

Date: August 21, 2002

  
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**APPENDIX A: REWRITTEN CLAIM WITH MARKINGS TO SHOW CHANGES**

1. (Twice Amended) A transcribed non-naturally occurring RNA molecule, comprising a desired [therapeutic] RNA portion, [wherein said molecule comprises an intramolecular stem formed by base-pairing interactions between a 3' region and a 5' complementary nucleotides in said RNA, wherein said stem comprises at least 8 base pairs, and] wherein said desired [therapeutic] RNA portion is present between [the] a 3' region and [the] a 5' [complementary nucleotides] region, wherein said 3' region and said 5' region form an intramolecular stem with each other comprising at least 8 base pairs.

6. (Twice Amended) The RNA molecule of claim 5, wherein said desired [therapeutic] RNA portion is at the 3' end of said B box of said RNA molecule.

7. (Twice Amended) The RNA molecule of claim 5, wherein said desired [therapeutic] RNA portion is in between said A and said B box of said RNA molecule.

8. (Twice Amended) The RNA molecule of claim 5, wherein said desired [therapeutic] RNA portion includes the B box of said RNA molecule.

9. (Twice Amended) The RNA molecule of claim 1, wherein said desired [therapeutic] RNA portion is selected from the group consisting of antisense RNA, decoy RNA, therapeutic editing RNA, enzymatic RNA, agonist RNA and antagonist RNA.

10. (Twice Amended) The RNA molecule of claim 1, wherein said 5' [complementary nucleotides] region of said RNA molecule [are] is able to base-pair with at least 12 bases of said 3' region.

11. (Twice Amended) The RNA molecule of claim 1, wherein the 5' [complementary nucleotides] region of said RNA molecule [are] is able to base-pair with at least 15 bases of said 3' region.

15. (Twice Amended) A cell in culture comprising the vector of claim 12.

16. (Twice Amended) A cell in culture comprising the vector of claim 13.

17. (Twice Amended) A cell in culture comprising the RNA of claim 1.

18. (Twice Amended) A method to provide a desired first RNA molecule in a cell in culture[,] comprising introducing into said cell a second RNA molecule comprising a 5' [terminus] region, a 3' [terminus] region, and said desired first RNA molecule, wherein [said 5' terminus is able to base pair with at least 8 bases of] said 3' region and said 5' region form an intramolecular stem with each other comprising at least 8 base pairs, and wherein said desired first RNA molecule is present between the [bases of the] 3' region and the 5' [terminus capable of base pairing in the second RNA molecule] region, under conditions suitable to provide the desired first RNA molecule in the cell.

24. (Twice Amended) The RNA molecule of claim 1, wherein said intramolecular stem is separated from said desired [therapeutic] RNA portion by spacer sequence.